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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,587	01/15/2002	Nabil L. Muhanna	M112 1100	4693

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EXAMINER	
MELSON, CANDICE C	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,587	MUHANNA, NABIL L.	
	Examiner	Art Unit	
	Candice C. Melson	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10,11,14,15,17-20,23,24 and 26-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6,7,27,29,30 and 32* is/are allowed.

6)☒ Claim(s) *1-4,8,10,11,14,15,17-20,24,26,28,31,33 and 34* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4,8,10-11,14-15, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not provide support for making the prosthesis of a resilient non-bone material being the only solid material of the body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1,,4,14-15, 17 -18, 20, 24,28, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz (USPN 4,349,921). Kuntz discloses, with respect to Claim 1, "one embodiment of the intervertebral disc prosthesis according to the invention is shown at 10 in FIGS. 1,2, and 3. The prosthesis 10 is formed of a thin block of biologically acceptable material having slightly convex superior and inferior surfaces 11 and 12, transverse grooves 13

in said superior and inferior surfaces and also in both lateral surfaces 14, 14, a flange or lip 15 raised from said superior and inferior surfaces at one longitudinal end of the prosthesis, and a wedge shaped tapering portion 16 at the other longitudinal end" (column 6, lines 9-18). This also anticipates Claim 15. As to Claim 14, the body has an anterior and posterior face. Furthermore, Kuntz teaches, "the wedge shaped tapering portion 16 allows for easier insertion of the prosthesis into the disc space" (column 6, lines 67-68). As to Claims 17-18, "the prosthesis 10 is essentially a spacer and can be fabricated from any biologically acceptable material of suitable strength and durability, for example high density polyethylene, polymethylmethylacrylate, stainless steel, or chrome cobalt alloys. The simplest material fabrication of the prosthesis is a polymer, preferably high density polyethylene" (column 7, lines 52-58). This also anticipates Claim 4. As to Claim 28, it is inherent that any foreign object must be sterilized prior to implantation within the body. With regards to Claims 31 and 34, a method of maintaining intervertebral space between adjacent vertebrae is disclosed wherein "the diseased discs are excised anteriorly and the space is thoroughly curetted out, removing the whole of the disc" (column 10, lines 18-20). "Once the space has been well curetted out to the posterior aspects of the body and while traction is being applied to the neck by the anesthetist, the intervertebral disc prosthesis 10 is tapped into position" (column 10, lines 32-35). Further with respect to Claim 20, Kuntz discloses that replacement of the lumbar disc "allows the surgeon to decompress any nerve roots or portion of the neural canal which are stenosed as part of the procedure. It also allows for excision of any free disc fragments" (col. 10, lines 61-64) It would have been an obvious matter of design choice to make the prosthesis to fabricate the body from a resilient non-bone material wherein this material is the only solid material of the body

since applicant has not disclosed that such a material solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with any other suitable biocompatible materials with any degree of resilience.

2) Claims 2-3,14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz in view of Gauchet (USPN 6,395,032). Kuntz discloses the claimed invention except for the body of the prosthesis made of a laminate comprising a plurality of layers. Gauchet's invention "provides an intervertebral disc prosthesis comprising a compressible cushion having a body made of a material, and a liquid which is able to come into contact with the body" (column 1, lines 47-49). "The prosthesis has a cushion 14 interposed between the plates 4. This cushion comprises bellows or folded laminate sheets 16. It has a shape, which is symmetrical in revolution about the axis 9. Its wall profile comprises corrugations which make it possible to vary the length of the bellows 16 in the axial direction" (column 2, lines 63-67). This reads on Claims 2-3. Also, as to Claim 2, the laminate 16 includes at least one fastener comprising an adhesive (column 3, lines 8-9). The prosthesis has an anterior face and a posterior face, as stated in Claim 14. As to Claim 19, "In this case, the bellows, like the plates, is made of titanium or titanium alloy so that is has a certain degree of axial strength and forms a compression spring" (column 3, lines 2-5). "The wall of the bellows can be made using one, two or three sheets each measuring 0.1mm in thickness" (column 3, lines 19-20). It would have been obvious to one having ordinary skill in the art at the time of the invention to make the body of the prosthesis from a laminate as taught by Gauchet, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

3) Claims 8,10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz in view of Boyer, III et al (US 2001/0039458). Kuntz discloses the invention as stated in Claim 8 except for the biocompatible material selected from a dissected animal and the dissected animal tissue selected from poreine and bovine tissue. As to Claim 10 Kuntz does not disclose the biocompatible material fixed by a protein cross-linking agent, in particular glutaraldehyde. Boyer, III et al teach a variety of bone grafting materials "another bone-grafting material is disclosed in US Pat. No. 4,678,470 to Nashef et al., and is formed using a tanning procedure involving glutaraldehyde that renders the material osteoconductive. A bone block is shaped into a precise predetermined form and size using conventional machining techniques. A paste-like suspension is also formed using known methods of comminuting bone, such as milling, grinding, and pulverizing, and adding the pulverized or powdered bone to a carrier. The treatment of glutaraldehyde allows the use of bovine, ovine, equine, and porcine bone sources. However, it the final desired form of the bone grafting material is a block of bone or machined shape, the bone stock must be large enough to provide a block of the required size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the tissue of a bovine as well as the protein cross-linking agent as taught by Boyer, III et al in order to provide a prosthesis that stimulates bone growth manufactured from a wider range of biocompatible tissue.

4) Claims 26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz in view of Ledergerber (USPN 6,187,043). Kuntz discloses the claimed invention except for a portion of the material is a ribbon. Ledergerber teaches an implantable prosthetic device where "in one embodiment, a complex woven PTFe filament or ribbon is sewn or affixed" (col.

3, lines 6-8). It would have been an obvious matter of design choice to fabricate a portion of the prosthesis from a ribbon, since applicant has not disclosed that such a material solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well without a portion being ribbon.

Allowable Subject Matter

Claims 6-7,27,29-30, and 32 are allowed.

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-4,8,10-11,14-15, and 17-19 have been considered but are moot in view of the new ground(s) of rejection. With regards to Claim 1, which now specifies that "the body comprises a resilient biocompatible, none-bone material, said material being the only solid material of the body", applicant argues that the amended claim clearly distinguishes over the cited references. The Examiner asserts that Applicant does not provide any support for the criticality of using a resilient non-bone material as the only solid material of the body of the prosthesis. Furthermore, in the specification on page 9, lines 9-23, Applicant states that "the material of the intervertebral disc prosthesis 10 of the present invention is any biocompatible material having a degree of resilience that can provide a level of shock

absorbance when the prosthesis is implanted in the spinal column of a patient". Applicant further discloses, "such biocompatible materials may be selected from, but are not limited to, a tissue dissected from a human or animal, a synthetic organic or synthetic inorganic polymer, or any combination thereof". Kuntz, in fact, anticipates the invention as stated n Claim 1 because it satisfies the limitations of the invention and furthermore discloses "fabricating the prosthesis 10 from any biologically acceptable material" (col. 7, lines 52-53). Kuntz even teaches away from manufacturing of "different materials bonded together" which is often done "to allow movement within the prosthesis" but as Kuntz teaches "this weakens the overall loading strength of the prosthesis", "particularly when the prosthesis is submitted to repeated stresses". Thus it is obvious that the material chosen as a matter of design choice may be non-bone and be the only solid material of the prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Candice C. Melson

Cary E. O'Connor
Primary Examiner